

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Atty. Docket No:

001107.00363

Elizabeth Jaffee et al.

Serial No.: 10/618,088

Group Art Unit:

1632

Filed:

July 14, 2003

Examiner:

**TBD** 

For:

MESOTHELIN VACCINES AND MODEL SYSTEMS

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA. 22313

Dear Sir:

Submitted herewith are two (2) sheets of Form PTO-1449. A copy of each of the references listed therein is enclosed. It is respectfully requested that the Examiner make his/her consideration of each of these documents formally of record.

Since this Information Disclosure Statement is being filed before issuance of a first Office Action on the merits under 37 C.F.R. 1.97(b), it is submitted that no fee or certification is required. However, if a fee is required, please charge our deposit account no. 19-0733.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Dated: May 18, 2004

Sarah A. Kagan

Registration No. 32,141

Banner & Witcoff, Ltd. Customer No. 22907

PTO/SB/08a (08-03)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the perwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitut	e for form 1449A/PT	0		Complete if Known			
.,	₽ <i>\$()€~</i>			Application Number	10/618,088		
INFO	RMATION	DIS	CLOSURE	Filing Date	July 14, 2003		
STA	STATEMENT BY APPLICANT			First Named Inventor	Elizabeth Jaffee		
				Art Unit	1632		
	(Use as many sh	eets as	necessary)	Examiner Name	TBD		
Sheet	1	of	2	Attorney Docket Number	001107.00363		

	U.S. PATENT DOCUMENTS						
Examiner	Cite	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant		
Initials *	No.1	Number - Kind Code <sup>2</sup> (if known)	MM-DD-YYYY	Cited Document	Passages or Relevant Figures Appear		
		US-5,320,956	06-14-1994	Willingham et al			
		US- 5,498,698	03-12-1996	Yamaguchi et al			
		US- 6,033,674	03-07-2000	Jaffee et al			
		US- 6,350,445	02-26-2002	Jaffee et al			
		US- 2003/0211498 A1	11-13-2003	Morin			
		US-					
		US-					
		US-		·			
		US-					
		US-					
		US-					
		US-					
		US-					
	Î	US-					
		US-					
		US-					

		FOREIGN PA	TENT DOCU	MENTS		
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document  Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
/	1	WO 93/13132 A1	07-08-1993	Yamaguchi et al.		*
pr.	1	WO 94/10312 A1	05-11-1994	Yamaguchi et al.		*
		EP 0 621 285 A1	10-26-1994	Yamaguchi, et al.:		*
		EP 0 517 925 A1	12-16-1992	Kondo et al.		*
	/	WO 97/24132 A1	07-10-1997	Jaffee et al.		*
	-	WO 98/53319 A2	11-26-1998	Vogelstein et al.		*
		WO 00/20027 A2	04-13-2000	Steinaa et al.		*
		WO 00/36107 A2	06-22-2000	Mitcham et al.		*
		WO 00/50900 A2	08-31-2000	Scholler et al.		*
	-	WO 01/18046 A2	03-15-2001	Xu et al.		*
		WO 01/57271 A2	08-09-2001	Penn et al.		•
		WO 01/57270 A2	08-09-2001	Penn et al.		•
	,	WO 01/92581 A2	12-06-2001	Algate et al.		*
	/	WO 02/00677 A1	01-03-2002	Birse et al.		*
		WO 02/055705 A2	07-18-2002	Mezes et al.		*

Examiner Signature	Date Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. Senter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Nind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08b(08-03) Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Poerwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO Complete if Known Application Number 10/618,088 INFORMATION DISCLOSURE Filing Date July 14, 2003 STATEMENT BY APPLICANT First Named Inventor Elizabeth Jaffee Art Unit 1632 (Use as many sheets as necessary) **TBD** Examiner Name 2 of 2 Attorney Docket Number 001107.00363 Sheet

## **FOREIGN PATENT DOCUMENTS**

1	WO 02/068677	09-06-2002	Mack et al.	*
-	WO 02/101075 A2	12-19-2002	Schlegel et al.	*
•	WO 02/102235 A2	12-27-2002	Mack et al.	*
	WO 03/014322 A2	02-20-2003	Azimzai et al.	*
	WO 03/042661 A2	05-22-2003	Afar et al.	*
•	WO 03/050243 A2	06-19-2003	Berger et al.	*

		NON PATENT LITERATURE DOCUMENTS		
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
	o	ARGANI, et al., "Discovery of New Markers of Cancer Through Serial Analysis of Gene Expression: Prostate Stem Cell Antigen Is Overexpressed in Pancreatic Adenocarcinoma," June 1, 2001, Cancer Research 61:4320-4324.		
	•	CHANG, et al., "Isolation and Characterization of a Monoclonal Antibody, K1, Reactive With Ovarian Cancers and Normal Mesothelium," 1992, Int. J. Cancer 50 (3):373-381.		
		CHANG, et al., "Characterization of the Antigen (CAK1) Recognized by Monoclonal Antibody K1 Present on Ovarian Cancers and Normal Mesothelium," January 1, 1992, Cancer Research 52:181-186.		
	,	CHANG, et al., "Molecular Cloning of Mesothelin, A Differentiation Antigen Present on Mesothelium, Mesotheliomas, and Ovarian Cancers," January 1996, PNAS USA 93:136-140.		
	(	HOUGH, et al., "Large-Scale Serial Analysis of Gene Expression Reveals Genes Differentially Expressed in Ovarian Cancer," November 15, 2000, Cancer Research 60:6281-6287.		
		JAFFEE, et al., "Novel Allogeneic Granulocyte-Macrophage Colony-Stimulating Factor-Secreting Tumor Vaccine for Pancreatic Cancer: A Phase I Trial of Safety and Immune Activation," January 1, 2001, Journal of Clinical Oncology 19(1):145-156.		
	,	KOJIMA, et al., "Molecular Cloning and Expressing of Megakaryocyte Potentiating Factor cDNA," 1995, The Journal of Biological Chemistry 270(37):21984-21990.		
		SCHAFER, et al., "Induction of a Cellular Immune Response to a Foreign Antigen by a Recombinant Listeria Monocytogenes Vaccine," July 1, 1992 <i>J. Immunology</i> , 149(1):53-59.		
		SUAREZ-ALVAREZ, et al., "Circulating IgG Response to Stromelysin-3, Collagenase-3, Galectin-3 and Mesothelin in Patients with Pharynx/Larynx Squamous Cell Carcinoma," 2001, Anticancer Research 21:3677-3684.		
		WAANDERS, et al., "Melanoma-Reactive Human Cytotoxic T Lymphocytes Derived from Skin Biopsies of Delayed-Type Hypersensitivity Reactions Induced by Injection of an Autologous Melanoma Cell Line," May 1997, Clinical Cancer Research 3:685-696.		
		YAMAGUCHI, et al., "A Novel Cytokine Exhibiting Megakaryocyte Potentiating Activity From a Human Pancreatic Tumor Cell Line HPC-Y5," 1994, <i>The Journal of Biological Chemistry</i> 269(2):805-808.		

Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-